

CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

**INITIAL STATEMENT OF REASONS FOR THE
PROPOSED ADOPTION OF INTELLECTUAL PROPERTY
REGULATIONS FOR FOR-PROFIT ORGANIZATIONS**

HEARING DATE: None scheduled.

SUBJECT MATTER OF PROPOSED REGULATIONS: Intellectual Property and Revenue
Sharing Requirements for For-Profit Organizations

SECTIONS AFFECTED: The proposed regulations adopt Chapter 4 and sections 100400, 100401, 100402, 100403, 100404, 100405, 100406, 100407, 100408, 100409 and 100410 of Title 17 of the California Code of Regulations.

SPECIFIC PURPOSE AND FACTUAL BASIS FOR EACH ADOPTION:

SECTION 100400 – SCOPE:

Purpose:

Section 100400 establishes the scope of the regulations comprising Chapter 4. The regulations in this chapter apply to all CIRM grant awards issued on or after the effective date of the regulations. Amended regulations become applicable to ongoing grants on the start date of the next non-competitive renewal period. Principal investigators, program directors and other officials with active grants will receive notification of revised grant terms as they are adopted by the CIRM.

Rationale: This section is necessary to define the circumstances and extent to which this chapter is to be applied. Because grants can exist over multiple numbers of years, it is necessary to indicate how revised grant terms are to be incorporated into existing grants.

**SECTION 100401 – INTELLECTUAL PROPERTY REGULATIONS –
DEFINITIONS:**

Purpose:

The following definitions shall apply to language contained in Sections 100400 through 100410 of these regulations.

(a) Award. The provision of funds by CIRM, based on an approved application and budget or progress report, to an organizational entity or an individual to carry out a project or activity.

(b) Awardee/Awardee Organization. The entity awarded a grant by CIRM that is legally responsible and accountable for the use of the funds provided and for the performance of the grant-supported project or activity. The awardee is the entire legal entity even if a particular component is designated in the Notice of Grant Award.

(c) Awardee Organization's Share. The revenues received by an awardee organization under a commercial license of a CIRM-funded patented invention remaining after deducting the direct costs associated with patents and patent applications claiming inventions made under CIRM funding and the inventor's share of those revenues.

(d) Biomedical Materials. Entities of biomedical relevance produced as a consequence of scientific research including but not limited to unique research resources such as synthetic compounds, organisms, cell lines, viruses, cell products, cloned DNA, as well as DNA sequences, mapping information, crystallographic coordinates, and spectroscopic data. Specific examples include specialized and/or genetically defined cells, including normal and diseased human cells, monoclonal antibodies, hybridoma cell lines, microbial cells and products, viruses and viral products, recombinant nucleic acid molecules, DNA probes, nucleic acid and protein sequences, certain types of animals including transgenic mice and other intellectual property such as computer programs.

(e) Exclusive License. Any License Agreement for a CIRM-funded patented invention that permits the licensee to exclusively exercise any commercial right within the state of California or the United States, or within any field of use, or for any licensed product or licensed purpose.

(f) For-Profit Organization. An organization, institution, corporation, or other legal entity that is organized or operated for the profit or financial benefit of its shareholders or other owners.

(g) Invention. A discovery that is or may be patentable (novel, useful and non-obvious) or otherwise protectable under Title 35 of the United States Code.

(h) License Agreement. An agreement by which a patent owner allows another party to make, use and/or sell an invention protected by a patent.

(i) Licensing Activities. Actions taken by authorized organizational officials, the desired outcome of which is a contractual agreement under which the grantee organization grants permission to another party to use intellectual property under specific conditions.

(j) Materials Transfer Agreement. A document which governs the exchange of a substance, element or item (material) to another party for the purposes of research. It limits the commercial exploitation of the material without the permission of the provider party.

(k) Principal Investigator/Program Director. The principal investigator ("PI") or program director ("PD") is an individual designated by the awardee to direct the project

or activity being supported by the grant, loan or contract. He or she is responsible and accountable to the grantee and CIRM for the proper conduct of the project or activity. For training programs or similarly structured programs, the PD is the same as the PI.

(l) Project period. The total amount of time for which CIRM promises to fund a grant, loan or contract and authorizes an awardee to conduct the approved work of the project described in the application.

Rationale:

To make specific the language and terminology used in formulating these regulations.

SECTION 100402 – INVENTION REPORTING REQUIREMENTS.

Purpose:

To ensure efficient use of CIRM-funded inventions, grantees are required annually to notify the CIRM of certain progress invention-related activities. This section identifies the information pertinent to such activities that must be reported in addition to any other information required by the CIRM under other regulations.

Subdivision (a) states awardees shall disclose patent application filings relevant to CIRM-funded inventions and describe with particularity the detail of the invention.

Subdivision (b) This subdivision requires awardees to notify the CIRM regarding issuance or non-issuance of patent applications.

Subdivision (c) requires notification regarding execution of any licensing agreements of patented inventions.

Subdivision (d) states awardees must maintain adequate records to account for revenue streams created as a result of CIRM-funded patented inventions and shall submit financial statements describing the revenues generated.

Rationale:

CIRM policy mandates that results and accomplishments of the activities it funds be made available to the public. Moreover, the CIRM is charged with ensuring that all grants and loan awards be subject to intellectual property agreements that balance the opportunity of the State to benefit from the patents, royalties and licenses that result from the research funded by the CIRM. (§ 125290.30, subd. (h).) To fulfill this role, the CIRM must monitor the work of grantees and ensure that inventions are pursued and exploited wherever possible. Therefore, this regulation is necessary to ensure that the CIRM is kept apprised whenever inventions are made and the steps taken or not taken regarding patents of those inventions. In addition, the reporting of licensing agreements

ensures that the CIRM is able to determine whether CIRM-funded inventions are being used appropriately in the search for therapies and cures.

SECTION 100403. PUBLICATION REQUIREMENTS.

Purpose:

This section identifies the procedures and content for publication of CIRM-supported research results. This section requires submission of copies of the publication to the CIRM, identification of where the MTA or similar document may be found, and a sample acknowledgment of CIRM funding.

Rationale:

CIRM policy mandates that results and accomplishments of the activities it funds be made available to the public. Moreover, the CIRM is charged with ensuring that all grants and loan awards be subject to intellectual property agreements that balance the opportunity of the State to benefit from the patents, royalties and licenses that result from the research funded by the CIRM. (§ 125290.30, subd. (h).) The CIRM also supports broad sharing of intellectual property of all kinds and encourages the timely publication of scientific articles in open-access journals that provide immediate access to scientific accomplishments by the scientific community and general public. It is the CIRM's intention to create a database for tracking CIRM-funded inventions, patent applications and license agreements that involve CIRM-funded patented inventions based on information received from grantee organizations. Non-confidential information about CIRM-funded intellectual property may be shared with the public through a CIRM annual report. As a result, this regulation is necessary to ensure CIRM is aware of CIRM-supported research results that the grantee deems worthy of publishing. The advance press release requirement also ensures the CIRM is kept abreast of and can report important progress of CIRM-supported research.

Subdivisions (a) through (c) ensure the CIRM can support sharing of research findings with the scientific community and the general public as a whole through the creation of a repository for such findings. This resource is intended to allow access by the scientific community and the general public to summaries of published scientific articles resulting from CIRM-funded projects. The regulation supports this disclosure by requiring abstracts to be written by the authors of scientific articles specifically for the general public and submitted to the CIRM within 60 days of the publication of the corresponding scientific articles.

SECTION 100404. PUBLICATION-RELATED BIOMEDICAL MATERIALS.

Purpose:

This section requires grantees to share biomedical materials described in published scientific articles for research purposes within a certain time after a receipt of a request

unless legally prohibited from doing so. The section provides for CIRM-approved deviation in some circumstances and provides that authors may provide requestors with information on how to reconstruct or obtain the material. The section requires materials to be shared without cost or at cost.

Rationale:

It is expected that intellectual property of all types will be created as a consequence of CIRM grants, loans and contracts. This regulation is intended to provide recipients of CIRM funding with guidance concerning appropriate terms for disseminating and acquiring unique research resources developed with CIRM funds and is designed to assist recipients in complying with their obligations under the Bayh-Dole Act and CIRM funding policy. In order to achieve maximum public benefit, data and biomedical materials (including research tools) should be as freely available as possible in the public domain.

SECTION 100405. PATENT APPLICATIONS:

Purpose:

This section states that grantees are responsible for bearing costs associated with patents and patent applications for CIRM-funded inventions.

Rational:

It is not a policy of the CIRM to fund costs associate with patent applications. This regulation is necessary to ensure grantees are aware of conditions of their award.

SECTION 100406. LICENSING CIRM-FUNDED PATENTED INVENTIONS:

Purpose:

This section describes the responsibilities of grantees for licensing activities of CIRM-funded patented inventions.

Subdivision (a) states it is the responsibility of awardees to pursue all licensing activities related to CIRM-funded patented inventions and must report that activity to the CIRM on an annual basis.

Subdivision (b) requires awardees to negotiate non-exclusive licenses of CIRM-funded inventions whenever possible and describes those circumstances under which exclusive licenses are permissible. In such circumstances, grantees must document the development and commercialization capabilities of the intended licensee and include terms addressing the therapeutic and diagnostic uses for which the invention is applicable.

Subdivision (c) requires awardees to include terms in exclusive licenses describing commercial development plans and relevant milestones for assessment of progress.

Subdivision (d) allows exclusive licenses for inventions relevant to therapies only to licensees with plans to provide access to resultant therapies at the time of commercialization for uninsured California patients. Licensees will be required to provide to patients whose therapies will be purchased in California with public funds at a discount price. Such plans may be made available by the CIRM to the ICOC for review.

Subdivision (e) requires awardees to monitor the performance of exclusive licensees to ensure timely development of the invention. This section provides for modification or termination of a license in the event that a licensee is unable to fully develop the rights granted.

Subdivision (f) requires awardees to negotiate grounds for modification or termination of the license and provides examples.

Subdivision (g) requires monitoring of development activities of licensees by awardees to determine compliance with the terms of the license agreement and must report those activities annually to the CIRM. **Subdivision (h)** requires awardees to modify or terminate license rights where necessary and to report such action to the scientific program officer at the CIRM.

Rationale:

Due to the importance of effective patent licensing to the development and availability of new products arising from CIRM-funded inventions, the CIRM licensing policy includes several important elements such as appropriate use of non-exclusive and exclusive licenses, diligent efforts to commercialize CIRM-funded inventions and plans for access to resultant therapies and diagnostics for qualified patients in California.

For inventions with potential preventive, diagnostic, or therapeutic uses, where some type of exclusivity (and therefore patent protection) is necessary for product development, licensing of the patent rights is the primary vehicle for transferring the technology to commercial partners.

Awardee organizations are responsible for licensing activities including identification of potential licensees, negotiation of license agreements and documentation of development progress. Awardee organizations are required elsewhere to submit a licensing activities report for CIRM-funded patentable inventions on an annual basis.

CIRM seeks to ensure development of each invention for the broadest possible applications, optimizing the number of products developed from CIRM-funded inventions. This is accomplished first and foremost through diligent assertion of inventorship rights to inventions in accordance with current patent law. In addition, CIRM policy is for awardees to retain those ownership rights for transfer to the private

sector through licensing instead of assignment. In the due diligence phase of licensing activities, awardee organizations are required to document the development and commercialization capabilities of the intended licensee, and include terms in the license agreement that address all relevant therapeutic and diagnostic indications for which the invention is applicable. This strategy allows CIRM awardees to engage in licensing negotiations which ensure the broadest and most expeditious development of new products.

CIRM encourages the use of non-exclusive licenses and recognizes that exclusive licenses may be required to enable development of therapies. Awardee organizations shall grant exclusive licenses involving CIRM-funded patented inventions relevant to therapies only to organizations with plans to provide access to resultant therapies and diagnostics for uninsured California patients. In addition, such licensees will agree to provide to patients whose therapies will be purchased in California by public funds the therapies at a discounted price. These access plans may be made available by CIRM for review by the ICOC and the general public on an annual basis.

CIRM seeks to ensure that licensees of CIRM-funded patented inventions obtain the appropriate scope of rights necessary for them to develop potential applications of the invention while optimizing public good through the widespread use of the invention.

SECTION 100407. ACCESS REQUIREMENTS.

Purpose:

The purpose of this section is to make the awardee aware of its obligation to provide at the time of commercialization a plan to CIRM that provides access to resultant therapies for uninsured Californians. The access plan must be consistent with industry standards existing at the time of commercialization, which plans may be reviewed by the ICOC and will be made available to the public.

Awardees also are required to provide therapies purchased in California with public funds at a discount price. For drugs, awardees agree to provide drugs purchased in California with public funds at a benchmark price identified in the California Discount Prescription Drug Program.

Where therapeutic products are in limited supply or have limited availability, awardees agree to give preference to California residents where feasible unless prohibited by law. In the event such preference cannot be accommodated, the awardee will explain in writing to the CIRM why it is unable to comply with this provision.

Rationale:

As a consequence of expenditure of the “first dollar” of CIRM funding, the for-profit awardee organization agrees to provide a plan (at the time of commercialization) to provide to uninsured California residents access to resultant therapies. The access plan

shall be consistent with industry standards extant at the time of commercialization. This will ensure that Californians without insurance are able nonetheless to have improved access to therapies developed with the financial assistance of California's taxpayers.

In addition, the awardees will provide the therapies at a discount price to residents whose therapies are purchased in California by public funds. For drugs generated as a consequence of CIRM funding, awardees agree to provide drugs at benchmarks described in the California Discount Prescription Drug Program (commencing with California Health and Safety Code section 130500, et seq.) to eligible Californians under that program. Awardees also agree to provide discount pricing for therapies in addition to drugs that result from CIRM funding.

SECTION 100408. REVENUE SHARING

Purpose:

This section describes the requirements of awardees with respect to the sharing of revenues obtained by licensing and developing CIRM-funded inventions.

Subdivision (a) describes the revenue sharing requirements when the awardee receives revenues as a result of licensing CIRM-funded patented inventions to third parties.

Subpart (1) states the rule that requires awardees to share a fraction of net revenues received in excess of \$500,000 and defines the term "net revenues." The rate of payment of the return to the State shall be negotiated between the awardee and the CIRM, but in no event shall be less than two (2) percent or more than five (5) percent of the annual revenue from the invention.

Subpart (2) allows awardees to retain up to \$500,000 in revenues, adjusted for inflation, before paying 17 percent of additional revenues to the State.

Subpart (3) states that where multiple funding sources have been used, in addition to CIRM funding, the return to the State shall be proportionate to the support provided by the CIRM. The awardee must submit to the CIRM the basis for its calculations of support at the time it discloses its patent application to the CIRM. The subpart restates CIRM's right to audit these calculations.

Subdivision (b) describes the rules for revenue sharing that pertain from self-commercialized products that result from CIRM-funded patented inventions.

Subpart (1) requires awardees to return up to three times the total CIRM award after revenues exceeding \$500,000, as adjusted for inflation, to be paid at the rate negotiated with the CIRM as set forth in subdivision (a)(1) of this regulation.

Subpart (2) requires awardees to submit to CIRM calculations to substantiate its assessment of CIRM support, which CIRM may audit.

Subdivision (c): This subdivision describes the rules that pertain for CIRM-funded projects that achieve blockbuster status by virtue of large revenue streams, as defined in each subpart.

Subpart (1) requires a one-time payment equal to three times the total CIRM award for revenues that exceed \$250 million per year and again when revenues exceed \$500 million per year.

Subpart (2) states that if CIRM has invested more than \$5 million in the research project AND a CIRM-funded patented invention was involved in the achievement of revenues equal to or greater \$500 million per year, CIRM requires payment of 1 percent of revenues in excess of \$500 million for the life of the patents.

Rationale:

Commercialization of stem cell research discoveries for public benefit is an expected outcome from CIRM funding. Current data suggest that discovery and development of a therapy can cost in excess of \$800 million. Although CIRM is not expected to completely fund the discovery and development of a stem cell-related therapy from start to finish, state funding may contribute in substantial ways to the commercialization of a product.

The California Stem Cell Research and Cures Act anticipates a return to the State of California:

The ICOC shall establish standards that require that all grants and loan awards be subject to intellectual property agreements that balance the opportunity of the State of California to benefit from the patents, royalties, and licenses that result from basic research, therapy development, and clinical trials with the need to assure that essential medical research is not unreasonably hindered by the intellectual property agreements.

Therefore, CIRM is expected to require that in the event of the creation of a revenue stream from commercialization of a CIRM-funded program, for-profit awardees will share a portion of such revenues with the State of California for deposit into the General Fund.

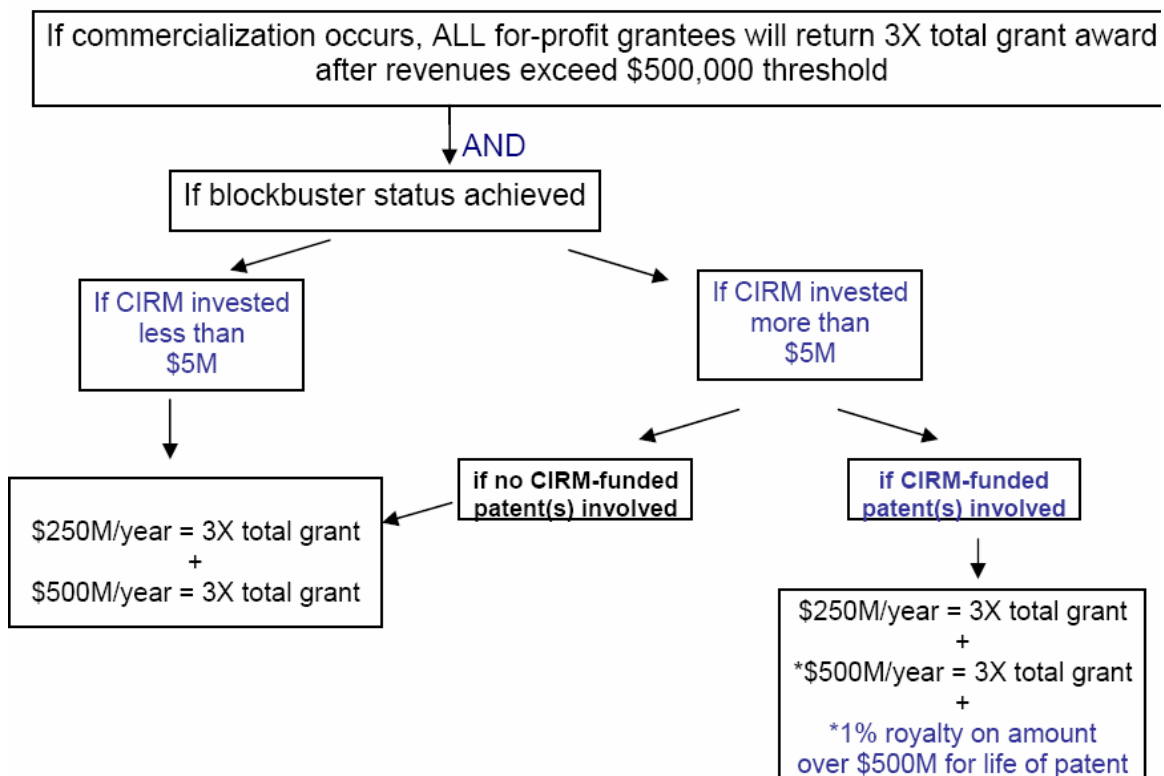
Given that most grants represent only a small fraction of the total funds needed to commercialize a product, a common theme of many biomedical research funding organizations that maintain payback expectations is consideration of the proportion of funding used to create the resultant product. Typically, this requires reporting of detailed calculations by the awardee to the funding entity to support claims made about proportional funds used in the commercialization of a product.

Awards to for-profit research organizations will be accompanied by specific agreements that describe payment expectations and time periods under which payments must be

made. Such agreements will be individually negotiated with the aim of ensuring that companies are not subject to undue risk as a consequence of payment schedules. In the negotiation of these agreements, CIRM recognizes that the selection of an appropriate royalty rate is required to successfully balance the expectation of the State of California for remuneration with the specific circumstances of the business position of the company. CIRM will use as its guide a royalty range of 2 to 5 percent as it negotiates the payment schedule for the expected capped return.

For-profit research organizations are structured to develop products for public benefit according to their research interests and business plans. As a consequence of this, it is likely that some CIRM for-profit awardees will intend to develop CIRM-funded projects for their own use rather than licensing rights to them to third parties. After extensive research, CIRM has developed proposed revenue sharing strategies to provide appropriate options in the best interests of the State of California. See the graphic below for a diagram of the revenue sharing structure.

For-Profit Revenue Sharing on “Self-Developed” Products



For grants made to for-profit organizations, the State of California will expect a return only in the event of successful commercialization of a product that stems from a CIRM-funded research project. Success will be defined as the receipt of revenues in excess of

\$500,000 from the CIRM-funded research-enabled product. In such cases, the State of California will receive three times the amount received under CIRM funding in the form of a capped royalty. For example, if CIRM awarded a \$1 million grant that ultimately gave rise to a product that generates revenue, the State of California is expected to receive of a total of \$3 million in royalty payments. The payment schedule will be negotiated using a royalty range of 2 to 5 percent to determine the rate at which the threefold return will be recovered.

For grants that lead to very successful commercial products, additional one-time blockbuster payments equal to three times the amount provided by CIRM is expected when revenues exceed \$250 million per year and when revenues exceed \$500 million per year. In the event that CIRM invested more than \$5 million (in aggregate) and a CIRM-funded patented invention was involved in the achievement of blockbuster revenues in excess of \$500 million per year, CIRM requires a 1 percent royalty on revenues in excess of \$500 million for the life of the patent(s).

SECTION 100409. PRESS RELEASE REQUIREMENTS

Purpose:

This section requires grantees to notify the CIRM prior to any press release that refers to certain activities regarding CIRM-funded research.

Rationale:

This regulation is necessary to the CIRM is apprised of current significant developments regarding CIRM-funded research and ensure proper attribution to the CIRM and the State of California for the CIRM-funded activity.

SECTION 100410. MARCH-IN RIGHTS

Purpose:

This section describes the circumstances under which the CIRM may exercise its right to require a grantee to grant an exclusive or non-exclusive license or exercise those rights itself.

Subdivision (a) states with regard to CIRM-funded patented inventions that the CIRM shall have the right to require the awardee, or exclusive licensee of a CIRM-funded invention, to grant a licensee in any field of use to a responsible applicant upon reasonable terms, and reserves the right of the CIRM itself to grant such a license if the awardee or licensee so refuses. The subdivision describes the circumstances under which the CIRM will act: 1) if the awardee or licensee has not made responsible efforts in a reasonable time to achieve practical application of a CIRM-funded patented invention; 2) if the licensee has failed to adhere to the given plan for access to resultant therapies; 3) failure by the licensee/awardee to adhere to requirements for public use; or 4) to alleviate a public health or safety emergency.

Subdivision (b) describes the process by which the awardee or licensee will be notified by the CIRM of its intent to exercise the rights described in this regulation and the timeline for allowing the licensee or awardee to cure the deficiency. This subdivision specifies that action taken by the CIRM to address a public health or safety emergency may be taken at any time.

Rationale:

CIRM maintains a mandatory licensing provision commonly referred to as the march-in authority, the purpose of which is to prevent the underutilization of CIRM-funded inventions. March-in would apply only to those research tools that could be defined as patentable inventions. Prior to exercising march-in rights, CIRM must determine that such action is necessary because of the failure of the awardee organization or its licensees to take effective steps to achieve practical application of the inventions in a particular field of use, to satisfy health or safety needs, or to meet requirements for public use. Unlike the research exemption license retained by CIRM, the march-in provision is not limited to use for research purposes. CIRM march-in rights may be exercised in the event of (but are not limited to) failure to license CIRM-funded patentable inventions, failure to meet plans outlined in license agreements, or failure to provide adequate availability of resultant products for the public use.

In observance of the march-in provision, awardee organizations may not assign to a third party all rights to an invention, although exclusive licensing is permitted under the CIRM IPPNPO.

CIRM will give to the awardee or licensee notice of such determination and the basis on which it was made. CIRM will not exercise its rights described above if the awardee or licensee takes diligent action promptly to cure the deficiency and such deficiency is cured not more than one year from receipt of notice (or longer period if agreed to by CIRM). With respect to a deficiency described in subdivision (a)(4), the CIRM may exercise such right at any time in the event of a public health or safety emergency. This is an appropriate tool in emergencies and is consistent with federal march-in provisions for federally-funded research.

*******END*******